

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/574,994
Filing Date	October 5, 2004 (I.A.)
First Named Inventor	Betty A. Diamond
Art Unit	to be determined
Examiner Name	to be determined
Attorney Docket Number	96700/1120

Sheet **2** of **4****NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	ABDEL-RAHMAN A. et al., "Disruption of the Blood-Brain Barrier and Neuronal Cell Death in Cingulate Cortex, Dentate Gyrus, Thalamus, and Hypothalamus in a Rat Model of Gulf-War Syndrome"; <i>Neurobiology of Disease</i> , 2002, Vol. 10, No. 3, pp 306-26.	
	2	ACR AD HOC COMMITTEE ON NEUROPSYCHIATRIC LUPUS NOMENCLATURE, "The American College of Rheumatology Nomenclature and Case Definitions for Neuropsychiatric Lupus Syndromes"; <i>Arthritis & Rheumatism</i> , 1999, Vol. 42, No. 4, pp 599-608.	
	3	BREY R.L. et al., "Neuropsychiatric syndromes in lupus - Prevalence using standardized definitions"; <i>Neurology</i> , 2002, Vol. 58, No. 9, pp 1214-20.	
	4	DEGIORGIO L.A. et al., "A subset of lupus anti-DNA antibodies cross-reacts with the NR2 glutamate receptor in systemic lupus erythematosus"; <i>Nature Medicine</i> , 2001, Vol. 7, No. 11, pp 1189-93.	
	5	DELLALIBERA-JOVILIANO R. et al., "Kinins and Cytokines in Plasma and Cerebrospinal Fluid of Patients with Neuropsychiatric Lupus"; <i>The Journal of Rheumatology</i> , 2003, Vol. 30, No. 3, pp 485-92.	
	6	DENBURG S.D. and DENBURG J.A., "Cognitive Dysfunction in Systemic Lupus Erythematosus"; in <i>Systemic Lupus Erythematosus</i> , Third Edition, Robert G. Lahita Editor, Academic Press, San Diego, CA, 1999, pp 611-29.	
	7	ELKON K.B. et al., "Antinibosomal Antibodies in Systemic Lupus Erythematosus"; <i>Rheumatic Disease Clinics of North America</i> , 1992, Vol. 18, No. 2, pp 377-90.	
	8	ESPOSITO P. et al., "Corticotropin-Releasing hormone and Brain Mast Cells Regulate Blood-Brain-Barrier Permeability Induced by Acute Stress"; <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 2002, Vol. 303, No. 3, pp 1061-66.	
	9	FRIEDMAN A. et al., "Pyridostigmine brain penetration under stress enhances neuronal excitability and induces early immediate transcriptional response"; <i>Nature Medicine</i> , 1996, Vol. 2, No. 12, pp 1382-85.	
	10	GAYNOR B. et al., "Peptide inhibition of glomerular deposition of an anti-DNA antibody"; <i>PNAS</i> , 1997, Vol. 94, pp 1955-60.	

Examiner Signature	Date Considered
---------------------------	------------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.58. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.N./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known

Application Number	10/574,994
Filing Date	October 5, 2004 (I.A.)
First Named Inventor	Betty A. Diamond
Art Unit	to be determined
Examiner Name	to be determined
Attorney Docket Number	96700/1120

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	11	HANLY J.G. et al., "Brain Pathology in Systemic Lupus Erythematosus"; The Journal of Rheumatology, 1992, Vol. 19, No. 5, pp 732-41.	
	12	HUGHES G.R.V. et al., "The Anticardiolipin Syndrome"; The Journal of Rheumatology, 1986, Vol. 13, No. 3, pp 486-9.	
	13	JOHN G.R. et al., "Cytokines: Powerful Regulators of Glial Cell Activation"; The Neuroscientist, 2003, Vol. 9, No. 1, pp 10-22.	
	14	JONGEN P.J.H. et al., Cerebrospinal fluid C3 and C4 indexes in immunological disorders of the central nervous system"; Acta Neurologica Scandinavica, 2000, Vol. 101, No. 2, pp 116-21.	
	15	KAO C-H. et al., "The role of FDG-PET, HMPAO-SPET and MRI in the detection of brain involvement in patients with systemic lupus erythematosus"; European Journal of Nuclear Medicine, 1999, Vol. 26, No. 2, pp 129-34.	
	16	KOZORA E. et al., "Magnetic Resonance Imaging Abnormalities and Cognitive Deficits in Systemic Lupus Erythematosus Patients Without Overt Central Nervous System Disease"; Arthritis & Rheumatism, 1998, Vol. 41, No. 1, pp 41-47.	
	17	LERITZ E. et al., "Neuropsychological Functioning and Its Relationship to Antiphospholipid Antibodies in Patients With Systemic Lupus Erythematosus"; Journal of Clinical and Experimental Neuropsychology, 2002, Vol. 24, No. 4, pp 527-33.	
	18	LERITZ E. et al., "Subcortical cognitive impairment in patients with systemic lupus erythematosus"; Journal of the International Neuropsychological Society, 2000, Vol. 6, No. 7, pp 821-5.	
	19	LIM M.K. et al., "Systemic Lupus Erythematosus: Brain MR Imaging and Single-Voxel Hydrogen 1 MR Spectroscopy"; Radiology, 2000, Vol. 217, No. 1, pp43-49.	
	20	NOMURA K. et al., "Asymptomatic Cerebrovascular Lesions Detected by Magnetic Resonance Imaging in Patients with Systemic Lupus Erythematosus Lacking a History of Neuropsychiatric Events"; Internal Medicine, 1999, Vol. 38, No. 10, pp 785-95.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.N./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number 10/574,994
Filing Date October 5, 2004 (I.A.)
First Named Inventor Betty A. Diamond
Art Unit to be determined
Examiner Name to be determined
Attorney Docket Number 96700/1120

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	21	NYLEN K. et al., "Cerebrospinal Fluid neurofilament and Glial Fibrillary Acidic Protein in Patients With Cerebral Vasculitis"; Journal of Neuroscience Research, 2002, Vol. 67, No. 6, pp 844-51.	
	22	PUTTERMAN C. and DIAMOND B., "Immunization with a Peptide Surrogate for Double-stranded DNA (dsDNA) Induces Autoantibody Production and Renal Immunoglobulin Deposition"; Journal of Experimental Medicine, 1998, Vol. 188, No. 1, pp 29-38.	
	23	SABET A. et al., "Neurometabolite Markers of Cerebral Injury in the Antiphospholipid Antibody Syndrome of Systemic Lupus Erythematosus"; Stroke, 1998, Vol. 29, No. 11, pp 2254-60.	
	24	SANNA G. et al., "Central nervous system involvement in systemic lupus erythematosus: cerebral imaging and serological profile in patients with and without overt neuropsychiatric manifestations"; Lupus, 2000, Vol. 9, No. 8, pp573-83.	
	25	SHARMA A. et al., "Studies of human polyclonal and monoclonal antibodies binding to lupus autoantigens and cross-reactive antigens"; Rheumatology, 2003, Vol. 42, pp 453-60.	
	26	SIBBITT, JR. W.L. et al., "Neuroimaging in Neuropsychiatric Systemic Lupus Erythematosus"; Arthritis & Rheumatism, 1999, Vol. 42, No. 10, pp 2026-38.	
	27	XAO H. et al., "Effect of LPS on the permeability of the blood-brain barrier to insulin"; Brain Research, 2001, Vol. 896, No. 1,2, pp 36-42.	

Examiner Signature	/Ronald Niebauer/	Date Considered	01/07/2010
--------------------	-------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 509. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.N./